

The 60 Plus Association

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*Tax Fairness for Seniors NO 461
Guardian of Seniors' Rights Award • Senior Voice Newsletter*

*Rep. Roger H. Zion, (R-IN, 1967-75)
Honorary Chairman*

*James L. Martin
President*

February 25, 2003

Mark McClellan, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Docket # 02P-0163/CP1

Dear Commissioner McClellan:

It was a real pleasure and honor to witness your swearing-in by Vice President Cheney. I'm confident President Bush has chosen wisely and senior citizens will be all the better for it.

On behalf of the nearly million members of the 60 Plus Association, we are writing today to express our opposition to efforts to forcibly switch entire categories of prescription drugs to over-the-counter status. We believe that these unprecedented and unwarranted actions place patient safety in harms way, encourages dangerous self-medicating practices, and places undue financial burden on the insured.

At issue is a citizens' petition by WellPoint Health Networks to forcibly switch newer non-sedating antihistamines to over-the-counter status, based on WellPoint's self-determined conclusion that the drugs are safe, effective and do not require physician supervision. In the wake of the Claritin switch in late 2002, WellPoint and other major health insurers quickly restricted access to prescription-strength non-sedating antihistamines and have actively pursued directing their beneficiaries towards purchasing over-the-counter versions of the new OTC drug.

We are very disturbed by the prospect that your agency would place the FDA's mission – to protect the public health – in jeopardy of being seconded to the desires of a for-profit entity. We can find no valid reason, besides the obvious financial interests of the petitioners, for the FDA to consider their request; on the contrary, we find overwhelming evidence that FDA should instead deny the petition.

In the case of America's elderly population, it is critically important that they maintain meaningful relationships with their physicians and other healthcare professionals. Typically, seniors are prescribed multiple medications for any number of chronic and acute conditions, which require precise dosage management and compliance under the supervision of a prescribing professional. One study reported that patients with severe respiratory disease (including chronic allergies¹) could be at risk of developing asthma, or patients susceptible to drug interaction complications, should continue to have their care overseen by a physician.

Distancing these seniors from the care of a doctor egregiously jeopardizes their health and well-being, and, incidentally, could serve to increase other healthcare expenditures, such as hospital visits to treat unnecessary overdosing or complications that arise from unforeseen contraindications.

We are also very concerned about the precedent that could be established if the FDA succumbs to the will of for-profit managed care. What other drug categories will HMOs deem worthy of these 'uncoverage' schemes, if they are successful with non-sedating antihistamines? Additionally, if the FDA decides to allow these drugs to be sold

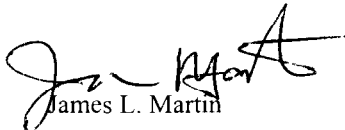
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over-the-counter, the notion of health insurance coverage is essentially set aside; seniors already living on fragile incomes will be forced to shoulder an added fiscal burden that in some cases is taken up now by a variety of health insurance alternatives. Why is the FDA playing any role in forcing seniors to choose between the needs for life-altering medication and the needs of food, shelter and other healthcare concerns?

America's growing senior citizen population will be on the front lines of medical and economic complications propagated by dangerous forced OTC switches. The FDA should not be acting as the pawn of managed care organizations looking to preserve market share on the backs of vulnerable senior citizens. We urge you to reject WellPoint's petition and keep vital decisions like OTC switches based on sound science and not subject to the whims of for-profit managed care.

Sincerely,



James L. Martin

Cc:

- Karen M. Templeton-Somers, Ph.D., Executive Secretary (Acting), Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857
- Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852, Email : fdadockets@oc.fda.gov

60 Plus is a 10-year-old nonpartisan group with a less government, less taxes approach to seniors' issues. 60 Plus is supported by donations from its estimated 435,000 citizen lobbyists to print and mail millions of letters, petitions, and voting indexes. 60 Plus publishes a newsletter, SENIOR VOICE, and a SCORECARD, bestowing a GUARDIAN OF SENIORS' RIGHTS award on lawmakers in both parties who vote "pro-senior." 60 Plus also presents a BENJAMIN FRANKLIN award to those who support death tax repeal as well as a LEGISLATOR OF THE MONTH award to the most pro-active friends of seniors in Congress. 60 Plus has been called 'an increasingly influential lobbying group for the elderly.'